THE ROSEN LAW FIRM, P.A.
LAURENCE ROSEN (LR-5733)
PHILLIP KIM (PK-9384)
275 Madison Avenue, 34th Floor
New York, N.Y. 10016
Tel. 212-686-1060/Fax 212-202-3827
lrosen@rosenlegal.com/pkim@rosenlegal.com

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel. DAVID MOORE, and STATE OF CALIFORNIA, ex rel. DAVID MOORE, and STATE OF DELAWARE, ex rel. DAVID MOORE, and DISTRICT OF COLUMBIA, ex rel. DAVID MOORE, and STATE of FLORIDA, ex rel. DAVID MOORE, and STATE of ILLINOIS, ex rel. DAVID MOORE, and STATE of INDIANA, ex rel. DAVID MOORE, and STATE of MICHIGAN, ex rel. DAVID MOORE, and STATE OF NEVADA, ex rel. DAVID MOORE, and STATE OF NEW MEXICO, ex rel. DAVID MOORE, and STATE OF NEW YORK, ex rel. DAVID MOORE, and STATE OF TENNESSEE, ex rel. DAVID MOORE, and STATE OF TEXAS, ex rel. DAVID MOORE, Plaintiffs, v. GLAXOSMITHKLINE, LLC Defendant.	Index No. 06-6047-CV Hon. Brian M. Cogan **RELATOR'S MEMORANDUM OF LAW IN OPPOSITION TO GLAXOSMITHKLINE LLC'S MOTION TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT**

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PRELIMINARY STATEMENT

During his employment as a marketing executive at GlaxoSmithKline, LLC ("GSK"), David Moore ("Relator") acquired first-hand knowledge of a deplorable scheme: GSK was paying kickbacks to medical providers to induce them to prescribe more Epzicom and Trizivir, two HIV drugs manufactured by GSK and primarily paid for by government health programs. Drawing on actual conversations with GSK's sales representatives and numerous physicians to whom GSK paid kickbacks, Relator's Second Amended Complaint ("SAC") exposes this lamentable fraud that enriched the pharmaceutical giant at the expense of the government and the vulnerable HIV patient population.

PROCEDURAL HISTORY

Relator filed an initial complaint under seal against GSK on November 9, 2006; an amended complaint followed on May 17, 2007. After a lengthy investigation, the United States entered a Notice of Election to Decline Intervention on August 24, 2012.[1] Relator elected to proceed with the action on behalf of the federal and various state governments, and filed the operative Second Amended Complaint on January 31, 2013.

ARGUMENT

The False Claims Act (FCA) punishes fraud on the government by imposing liability on any party who "knowingly presents, or *causes to be presented*, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1) (emphasis added). To be liable under the FCA, a person need not have submitted the false claim himself. "The Supreme Court has long held that

1 On July 2, 2012, GSK had just pled guilty to criminal charges and agreed to a $3 billion settlement with the United States relating in part to illegal kickback schemes involving certain GSK drugs, including Imitrex, Lotronex, Flovent, and Valtrex. The $3 billion settlement represents the largest healthcare fraud settlement in history.

a non-submitting party may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct." *U.S. ex rel. Hutcheson v. Blackstone Medical, Inc*., 647 F.3d 377, 390 (1st Cir. 2011). Hence a company like GSK can be liable under the FCA for causing others, such as medical providers, to submit false claims to the government.

A claim may be "false" if the submitting party certifies compliance with a statute or regulation that is a precondition for payment, but the party is not actually in compliance with that statute or regulation. *New York v. Amgen, Inc.*, 652 F.3d 103, 108-109, (1st Cir. 2011), *accord Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001). Thus an underlying violation of the Anti-Kickback Statute (AKS) renders a claim false under the FCA if a party had certified compliance with the AKS as a precondition to receiving payment. *See e.g. Mikes v. Strauss*, 274 F.3d at 697 (holding that a claim under the FCA is false where "a party certifies compliance with a statute or regulation as a condition to governmental payment); *Hutcheson*, 647 F.3d at 393 ("These two [certifications] are more than specific enough to make clear that the claims submitted by hospitals represented that any underlying transactions had not involved third party kickbacks prohibited by the AKS."); *U.S. ex re. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) (submitting claims for payment while not in compliance with the AKS is a fraud actionable under the FCA because "[t]he Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback" (quoting Government's amicus curiae)). As alleged in the SAC, medical providers must certify their continuing compliance with the AKS in order to participate in Medicaid and Medicare, and any violation of the AKS renders the providers' certification false. *See, e.g.* SAC ¶¶ 34-37. In

addition, the medical providers' claim forms to the government for payment contain a similar certification of compliance with the AKS. *Id*.

Relator draws on actual conversations with GSK sales representatives and medical providers, as well as eyewitness accounts of "agreements" between GSK sales representatives and medical providers, to plead with exacting detail the particularities of a kickback scheme orchestrated by GSK to induce physicians to prescribe more Epzicom and Trizivir. Additionally, Relator provides cogent statistical support along with specific allegations to show that the kickbacks caused medical providers to submit false claims to the government. As detailed below, Relator's complaint more than meets what is required at the pleading stage.

A. <u>The SAC satisfies all applicable pleading standards</u>

a. Relator need only plead a plausible claim under 12(b)(6)

On a motion to dismiss, courts must accept the factual allegations as true and draw all reasonable inferences in plaintiff's favor. *See, e.g. Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). Moreover, plaintiff needs only "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *accord Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009) ("[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the conduct alleged."). Plaintiffs must only "nudge[] their claims across the line from conceivable to plausible. *Twombly*, 550 U.S. at 570. Plausible does not mean "probable;" rather, plausibility requires only that there be more than a "sheer possibility" that a defendant is liable for the alleged misconduct. *Iqbal*, 129 S.Ct. at 1949. Relator's complaint exceeds this modest threshold.

b. GSK mischaracterizes the pleading requirements under 9(b)

GSK attempts to raise the pleading standard by erroneously asserting that Relator

must allege details of "specific claims for payments that were submitted to the government" or the specific details of an actual Medicaid/Medicare provider certification form signed by a particular physician. GSK's position, however, has been emphatically rejected by courts all over the country.

The prevailing standard is that a relator need not plead the specifics of an actual claim; the relator is only required to show reliable indicia that false claims were submitted. For example, in *U.S. ex rel Schumann v. AstraZeneca PLC,* 2010 WL 4025904 (E.D.Pa, Oct. 13. 2010), the court held that claims under the FCA "need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." 2010 WL 4025904 at *9 (quoting *U.S. el rel Lemmon v. Envirocafre, Inc.*, 2010 WL 3025021 (10th Cir. 2010)). The *AstraZeneca* court reasoned:

> Requiring the relator to plead the details of an actual claim would not place AZ in a better position to answer and defend the charges of fraud against it. Here, the "false claims" are only false because they are based on the kickback fraud between AZ and Medco or the "false" best price reports submitted by AZ. If the relator had described the details of an actual claim submitted by a government-plan patient or state Medicaid office and included specifics, such as the contents of the claim, who submitted it, the date, the amount claimed, and the amount actually due, AZ would not be in a better position to defend itself because neither the patients nor the states are being charged with fraudulent conduct. A case should not turn on whether a pointless allegation has been pled or not.

Id. at *9.

This proposition finds support in numerous circuits. In *United States ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 189 (5th Cir. 2009), the court ruled that a *qui tam* plaintiff does not need to allege the time, place, and contents of the false representation in every case, because requiring this level of detail is "one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly

more than any federal pleading rule contemplates." Therefore, "to plead fraud with particularity...a relator's complaint, if it cannot allege details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. *See also, U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, 2012 WL 2871264 (S.D.Fla. July 12, 2012) (identification of specific claims is one way to satisfy 9(b), but is not the only way); *Seville Indus. Machinery Corp. v. Southmost Machinery Corp.*, 742 F.2d 786, 791 (3d Cir. 1984) (specific allegations of date, time, place of an actual false claim is not required; appropriate to use "alternative means of injecting precision and some measure of substantiation into" allegations of fraud); *U.S. ex rel. Kennedy v. Aventis Pharm. Inc.*, 512 F.Supp.2d 1158, 1167 (N.D.Ill. 2007) (complaint complied with 9(b) where the relator alleged facts regarding defendant's off-label marketing – but no specific claims – because such information was unlikely "to be within the relators' reach" and [g]iven the significant proportion of medical care in this country that is financed by Medicare and Medicaid"); *U.S. ex rel. Taylor v. Gabelli*, 345 F.Supp.2d 313, 326 (S.D.N.Y. 2012) (relaxing 9(b) pleading requirements where fraudulent conduct occurred over a number of years); *Strom ex rel. United States v. Scios, Inc.*, 676 F.Supp.2d 884, 894 (N.D.C.A. 2009) (action could go forward because the "[t]he gravamen of this action concerns fraudulent inducement of doctors, and the Complaint provides exhaustive allegations relating to this fraud," even though no details of fraudulent claims were submitted, the allegations nevertheless "put defendants on sufficient notice of the nature of the action.").

Hence the pleading standard under 9(b) is far from the prohibitive and unreasonable burden trumpeted by GSK. Relator has more than pled an adequate basis for the Court to make the reasonable inference that a false claim was indeed submitted. That is all that 9(b) requires.

For example, the SAC alleges that GSK sold hundreds of millions of dollars of Epzicom and Trizivir in the U.S. each year and that approximately 80% of the total was paid for by government health programs, including Medicare, Medicaid, and ADAP. SAC ¶ 22. Thus it is more than plausible – highly probable – that at least one of the Epzicom/Trizivir prescriptions filled by the medical providers who received kickbacks from GSK was paid for by the government. This allegation alone is sufficient for the inference that a false claim was submitted to the government. GSK's suggested inference borders on fantasy (and is also improper at the motion to dismiss stage): that none of the medical providers who received kickbacks participate in Medicaid or Medicare, or that those medical providers only prescribed Epzicom and/or Trizivir to patients who were NOT covered by Medicaid, Medicare, or ADAP. These inferences are not only far-fetched, but also represent the types of inferences in favor of defendants that are impermissible when deciding a motion to dismiss.

Additionally, the SAC provides specific allegations of false claims. For example, according to Paragraph 74 of the SAC:

> As one doctor, Jed Burack, explained to the Relator, GSK was simply "paying for a prescription." Dr. Dianna Williamson told relator that she was aware of a specific "phase IV clinical trial" on Epzicom's hypersensitivity that GSK was asking doctors in New York to participate in by simply filling out some paperwork and writing an Epzicom prescription in return for $500. Williamson also said that the pharmacies that provide the medications charge the costs to Medicaid, even though GSK should be providing the medication for free. Williamson stated that some of the doctors who are receiving these payments for participating in the "studies" are Mark Johnson, Joe Oliveri, and Alan Stein. When GSK first asked Dr. Olivieri to participate in this study, he was not prescribing any Epzicom.

SAC ¶ 74 (emphasis added).

GSK cites a number of cases to support its assertion that specifics concerning an "actual false claim" must be pled, but those cases contain factual distinctions that make them inapplicable here. For example: in *United States ex rel. Smith v. N.Y. Presbyterian Hospital*,

2007 WL 2142312 (S.D.N.Y. July 18, 2007), the relator does not list a single N.Y. Presbyterian Hospital employee who is alleged to have been involved in submitting false claims. In comparison, Relator's SAC specifically names medical providers who participated in the kickbacks and prescribed more Epzicom and Trizivir as a result. Similarly: *Piacentile v. Novartis*, 1:04-cv-4265 at 15 (E.D.N.Y. Feb 8, 2011) ECF No. 84 (plaintiff does not specify any doctors, or what types of claims were submitted); *United States ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582 (E.D.N.Y. May 22, 2009) (relator fails to identify a single doctor who received or viewed the Lipitor marketing materials).

Moreover, GSK quotes *United States ex rel. Clausen v. Laboratory Corp. of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002) for the proposition that Rule 9(b) cannot be satisfied by alleging that "...the claims requesting illegal payments *must have been submitted, were likely submitted or should have been submitted* to the Government." Defendant's MOL at 7 (emphasis in original). GSK's incomplete, and selective, quotation of *Clausen* is misleading, because the full sentence actually reads:

> As such, Rule 9(b)'s directive that "the circumstances constituting fraud or mistake shall be stated with particularity" does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government. As in Cooper, and as with every other facet of a necessary False Claims Act allegation, if Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government.

290 F.3d at 1311 (emphasis added).

This is consistent with Relator's position that as long as there is "some indicia of reliability" concerning a false claim, specific details about an actual false claim is not necessary.

Relator's interpretation of *Clausen* finds support in *Osheroff*, 2011 WL 2871264.

There, the court held that: "the Eleventh Circuit does not construe *Clausen* to require identification of specific claims...[t]he panel explains that *Clausen* required that 'some indicia of reliability must be given in the complaint to support the allegation of fraud' to satisfy Rule 9(b)." *Id.* at 5 (quoting *United States ex rel. Singh v. Bradford Regional Medical Ctr.*, 2006 WL 2642518 (W.D.Pa. Sept. 13, 2006).

GSK's characterization of what is necessary to plead a false claim under 9(b) is thus greatly exaggerated. Because no specific details of an actual false claim are necessary, and the SAC provides cogent facts to support a reasonable inference that false claims were submitted, Relator survives a motion to dismiss if he also sufficiently pleads an underlying fraudulent scheme.

B. <u>Relator sufficiently pleads an underlying fraudulent scheme</u>

GSK next argues that Relator has failed to plead an underlying fraudulent scheme. As shown below, GSK's contentions are entirely meritless.

a. GSK's "fair market value" argument is illogical and Relator has pled that GSK's payments exceeded fair market value

GSK contends that Relator failed to provide sufficient detail concerning why any payment that GSK made to the physicians was anything but market value for a legitimate service. This argument fails for two reasons.

First, Relator states with precise detail that GSK's payments were higher than those of GKS' main competitor, Gilead. When asked by Gilead why he was not prescribing more of Gilead's HIV medication, a certain Dr. Brutus replied: "Glaxo pays $2,500. You guys pay $1,800, down from $2,000 but we can do more programs." SAC ¶ 61. Indeed, Relator alleged that GSK paid 40% more money to HIV doctors for "programs" than Gilead did. SAC ¶ 62.

GSK now asks that the court infer that Gilead somehow chose to pay below market value (thereby making GSK's payments "market value"). This is not a permissible inference in favor of the defendant at the pleading stage.

Secondly, the SAC contains numerous allegations that in many instances, GSK paid physicians to do nothing. For example: paying doctors "honorariums" for not providing any services or other consideration to GSK and in some cases paying doctors for programs that never took place, SAC ¶¶ 64-65 (e.g. "Relator asked Etkins who else he's arranging honorariums for that don't do any programs or don't provide any services to GSK and Etkins answered Dr. Cary English, Dr. Ngozi Oji, and Dr. Karl Latortue."); paying doctors for "round-table" dinners where nobody but the physician and the GSK sales representative were present, SAC ¶¶67, 69. The only reasonable, fair market value for doing nothing is $0.

b. Relator has adequately pled that GSK acted with scienter

GSK further argues that Relator does not provide sufficient facts to support an inference that GSK acted with scienter. GSK once again overstates the pleadings standards for this requirement.

The 1986 Amendments to the FCA, which added the scienter requirement, "were not intended to create a burdensome obligation. Rather, the appropriate test is whether the defendant's actions were reasonable and prudent under the circumstances." S.Rep. No. 99-345, at 21 (1986), reprinted 1986 U.S.C.C.A.N. 5161, 5286. Courts in this circuit have held that a "strong inference of fraudulent intent" can be pled in two ways: "First, the plaintiff may allege a motive for committing fraud and a clear opportunity for doing so. Second, where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious behavior by the defendant, though the strength of the circumstantial allegations must be

correspondingly greater." *U.S. ex rel. Taylor v. Gabelli* 345 F.Supp.2d 313, 328 (S.D.N.Y. 2004) (citing FN67 *Powers v. British Vita, P.L.C.*, 57 F.3d 176, 184 (2d Cir.1995) (citations, quotation marks, and alterations omitted)).

GSK can hardly suggest it had no motive. Epzicom and Trizivir are classified as "alternative" and "inferior" HIV drugs by the HHS Guidelines, medically indicated for fewer than 2% of new HIV patients. SAC ¶¶ 77-78. Yet, they command a staggering market share of HIV drugs prescribed by the physicians whom received kickbacks from GSK. For example, as of January 2007, Epzicom had a 31% market share with Dr. Exhihomme and a 21% market share with Dr. Hsu, both of whom received payments from GSK for programs that never took place. SAC ¶63. Through its fraudulent kickback scheme, GSK has increased its market share from 2% to 8% nationwide and to almost 13% in Brooklyn. SAC ¶77. Given that GSK earned over half a billion dollars from its HIV drugs in 2006, its motivation to increase sales is unassailable. SAC ¶ 22.

GSK advances the naïve argument that because GSK employees and the doctors "openly discussed" these purported kickbacks, their arrangements must have been legitimate. GSK's argument contravenes the actual language of the AKS, which specifically bars remunerations that were solicited or received "directly or indirectly, overtly or covertly." 42 U.S.C. 1320a-7b(b)(1). Hence just because an "agreement" was overtly discussed does not make it lawful and legitimate. Surely GSK is not suggesting that only "agreements" made in a vacant parking lot in the middle of the night carry inferences of scienter.

Nevertheless, numerous specific allegations in the SAC support an inference of scienter. For example, Relator alleges that beginning in about 2003, GSK sometimes used a third-party company to "administer these programs" and funnel the checks to the physicians so as to conceal

the nature of the payments on GSK's books and records. SAC ¶ 66. Furthermore, statements as such "You give me more Epivir and I'll give you a $35,000 dollar grant," (SAC ¶ 71) and admissions that GSK paid doctors to do nothing renders farcical GSK's contention that no GSK employee "made statements implying that they believed there was something untoward about the company's relationship with physicians." Defendant's MOL at 15. And indeed, Relator, a GSK employee at the time, "told Etkin [another GSK sales manager] that he is crazy making payments to doctors who don't even do programs. Etkin responded that he's been doing it a long time." SAC ¶65. And Etkin named other doctors to whom he was directing payments even though the doctors were not providing any services to GSK. *Id*.

In any event, scienter is a fact-intensive inquiry that courts should not resolve at the motion to dismiss stage. *See. e.g. U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.* 498 F.Supp.2d 25, 57 (D.D.C. 2007) (scienter is "often a fact-bound inquiry"); *Mason v. Medline Industries, Inc.*, 731 F.Supp.2d 730, 736 (N.D.Ill., 2010) (whether defendant's actions were legitimate business practices or kickbacks raises questions of fact not appropriate for resolution on a motion to dismiss); *United States v. Estate of Rogers*, 2001 WL 818160 (E.D.Tenn, June 28, 2001) (the scienter element of the FCA is a matter for the jury to determine at trial).

c. It is not necessary to describe a scheme outside of NY to plead a nationwide scheme

At the pleading stage, Relator needs not describe a nationwide scheme. Where the relator adequately alleges a claim in one state or region, such pleading satisfies Rule 9(b) by establishing a nationwide inference of fraud. *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009) (allowing evidence of eight providers' false claims to support a strong inference that such claims were also filed nationwide). *See also, U.S. ex rel. King v.*

Solvay S.A., 823 F. Supp.2d 472, 498 (W.D.Pa., 2006) ("the examples of Texas physicians who prescribed Solvay drugs after receiving kickbacks lead to a strong inference that this also happened in other parts of the country"); *U.S. ex rel. Carpenter v. Abbott Laboratories, Inc.*, 723 F.Supp.2d 395, 409-10 (D.Mass. 2010) (allowing action to go forward in twelve other states even though relator only alleges facts pertaining to a scheme in Massachusetts).

GSK cites cases that are irrelevant here. In both *U.S. ex rel. Ge v. Takeda Pharm. Co.*, 2012 WL 5398564 (D.Mass. Nov. 1, 2012) and *U.S. v. Center for Diagnostic Imaging, Inc.*, 787 F.Supp.2d 1213 (W.D.Wash. 2011), the relator failed to sufficiently plead an action with requisite particularity in any state. Similarly, in *U.S. ex rel. Thomas v. Bailey*, 2008 WL 4853630 (E.D.Ark. 2008), the relator bases his nationwide allegations on the supposed presence of a nationwide "corporate policy" but then failed to allege any details about this corporate policy.

GSK next attempts to distance itself from the "purported actions of a single rogue employee in New York." Defendant's MOL at 12. This is nothing short of a Hail Mary attempt at exculpation. The SAC alleges that GSK's compliance guidelines required all payments to doctors in excess of $300 must be approved and signed off by a regional manager. SAC ¶ 76. Moreover, the SAC alleges that another GSK employee, Ron Lesniewski, participated in the sham "round-table" dinners with doctors. SAC ¶ 67. Therefore the SAC, and the concept of *respondeat superior*, hardly allow GSK to dismiss Relator's allegations by flippantly attributing a scheme to "one rogue employee."

d. Relator's allegations were not based on mere "information and belief"

GSK's accusation that Relator attempts to plead a kickback scheme based on pure "information and belief" is entirely inaccurate.

The SAC is packed with statements from GSK employees and the physicians to whom GSK paid kickbacks – based on their first-hand knowledge. These statements about kickbacks are numerous and corroborative of a kickback scheme. *See e.g.* SAC ¶¶ 64, 65 (admission from GSK sales representative that certain doctors were routinely paid thousands of dollars for programs that never took place); ¶67 (statement from doctor stating that GSK would pay her $1,500 to participate in sham "round-table" dinners where nobody shows up); ¶71 (GSK sales representative bluntly telling a doctor "You give me more Epivir and I'll give you a $35,000 grant."); ¶74 (doctor telling Relator that GSK was "simply paying for a prescription"). These represent first-hand account of statements that were either told to the Relator or witnessed by the Relator; none of them were based on "information and belief."

GSK's identification of two allegations (SAC ¶¶ 75, 77) where the words "believes" and "understands" were used hardly renders the SAC as one that "relies" on "information and belief." In one, Relator "believed" the amount GSK paid to Dr. Hsu to accompany GSK salesmen on sales calls was"$2,250". Only the specific dollar amount is stated with belief, not the fact of the payment or its purpose. In the other, "Relator understands that Epzicom is medically indicated for less than two percent (2%) of new HIV patients," SAC ¶77. GSK's point is irrelevant because Relator alleges the same facts in an earlier paragraph without using the term "understands". ("Despite its second-tier status, which makes it medically appropriate for less than two percent of HIV patients ….) SAC ¶50. Moreover, the three allegations that GSK dismisses as "hearsay statements" from a GSK competitor (SAC ¶¶ 68-70) merely serve to further bolster and provide additional anecdotal support for Relator's account of a kickback scheme. Nonetheless, hearsay is permissible in complaints. *In re Air Disaster at Lockerbie, Scotland, on Dec. 21, 1988*, 144 F.R.D. 613, 617 (E.D.N.Y. 1992) (holding that complaints may

be based on "hearsay reports and statements of others").

e. Relator has pled that the kickbacks induced physicians to write more Epzicom and Trizivir prescriptions

GSK's argument that Relator fails to show that there was any causal relationship between the illicit payments and the writing of Epzicom and Trizivir prescriptions is baseless and does not stand up to the well-pled facts.

First, the SAC makes specific allegations where either GSK employees or the physicians who participated in the kickback scheme admitted that the kickbacks were aimed at inducing, and did induce, physicians to prescribe more Epzicom and Trizivir than they otherwise would have. *See e.g.*, SAC ¶ 71 (GSK offered "unrestricted educational grants" to induce physicians to write a high volume of prescriptions for Epzicom and Trizivir. GSK's Etkins told Dr. Williamson: "You give me more Epivir and I'll give you a $35,000 grant."); ¶ 74 (two doctors stating that GSK asked doctors to fill out some simple paperwork and write an Epzicom prescription in return for $500); ¶ 61 (Dr. Brutus telling Gilead that the reasons he's "below the national average" for prescribing Gilead HIV medications is because GSK pays him more kickbacks, implying that GSK's kickbacks have resulted in his writing more Epzicom and Trizivir prescriptions).

Second, the SAC provides overwhelming statistical evidence that GSK's kickbacks have led to physicians' writing more Epzicom and Trizivir prescriptions.[2] Because of its potentially fatal side effects, Epzicom has been deemed an "alternative" drug by the HHS

2 Courts in this Circuit permit the use of statistics to raise inferences of causation. *See e.g.*, *Hogan v. Metromail*, 167 F.Supp.2d 593 (S.D.N.Y. 2001) (holding that statistics support an inference of causation sufficient to defeat a motion to dismiss in an employment discrimination case where plaintiff alleges that employees aged 40 or above represent 63% of the company's workforce, and yet constitute 93% of those who were affected by the challenged employment practice).

Guidelines and is medically indicated for fewer than 2% of new HIV patients. SAC ¶¶ 46-51, 77. Yet, Epzicom is being prescribed for approximately 12.8% of new HIV patients in Brooklyn, where the doctors named in the SAC as having received kickbacks practice. SAC ¶ 50. The percentage amounts of GSK's second tier HIV medications being prescribed by the specific doctors who received GSK's kickbacks are even more startling. As of January 2007, Dr. Exhihomme prescribed Epzicom to 31.2% of his patients, Dr. Brutus 37.0 %[3] and Dr. Hsu did so for 21.2% of his patients. SAC ¶¶59, 65. Another doctor who received illicit payments from GSK, Dr. Olga Wildfeuer, prescribed Epizcom for approximately one out of every four HIV patients. SAC ¶ 67. These are staggering figures for a drug that is medically indicated for fewer than 2% of HIV patients, and one that is only prescribed at a national average of 8% (a figure that itself may be inflated due to GSK's kickbacks). It is no sheer coincidence that doctors who received kickbacks are prescribing Epzicom at three, or four times the national average (and two or three times the average for Brooklyn). Additionally, Relator estimates that the 400 physicians GSK's HIV division paid as "speakers" were responsible for writing more than 80% of its HIV medication prescriptions nationwide. SAC ¶73.

GSK twists facts (and logic) by asserting that because 92-95% of HIV patients do not develop hypersensitivity in response to Epzicom and Trizivir, it is not unreasonable that Epzicom commands a 12.8% market share in Brooklyn. However, just because 92-95% of HIV patients will not be seriously harmed by Epzicom and Trizivir does not meant that the two drugs are the preferred, or even the appropriate, drug for 92-95% of the population. As mentioned several times *supra*, the HHS Guidelines categorize Epzicom and Trizivir as "alternative" and "inferior" drugs, making them appropriate for fewer than 2% of the HIV population. According to a

3 Dr. Brutus was the highest volume prescriber of Epzicom in the United States. SAC ¶59.

nationally-recognized HIV physician, the HHS Guidelines establish the "standard of care and a physician must have a very strong reason for deviating from the Guidelines." SAC ¶78. Hence the correct way to interpret the numbers is: Epzicom is not appropriate for 98% of the HIV population, and yet, it commands a 12.8% market share in Brooklyn, and up to 37.0% for doctors who received GSK kickbacks. These statistics, at the very least, raise a compelling inference of causation sufficient to defeat a motion to dismiss.

GSK asserts that many doctors may have a legitimate basis to prescribe GSK's second-tier medicines. However, the 8% national market share average for Epzicom already takes into account these instances of doctors deviating from the standard of care and exercising their medical judgment to prescribe GSK's medications. What the SAC shows is that doctors receiving payments from GSK are writing prescriptions for GSK's medications that exceed this national average by three or four times. Medical discretion cannot account for this statistical anomaly. Nor does GSK justify why doctors receiving payments from GSK are writing prescriptions for its medications at such high levels, relative to doctors not receiving any payments.

GSK advances the irrelevant argument that permitting *qui tam* plaintiffs to assert that doctors' quality of care failed to meet medical standards would promote federalization of medical malpractice. This again conflates the issue at hand. Relator is not basing the SAC on allegations of medical malpractice or doctors providing services below the standard of care, but rather on a pattern of flagrant violations of the AKS. There should be no concern whatsoever about the "federalization of medical malpractice" here because the allegations of false claims are based on the underlying fraudulent kickback scheme orchestrated by GSK. Any facts about standards of medical care advanced by Relator only go towards bolstering the conclusion that

GSK's kickbacks are causing doctors to write more prescriptions for Epzicom and Trizivir.

f. The Medicare Provider Agreement requires compliance with the AKS

In a footnote, GSK asserts the curious argument that during the time period covered by the SAC, the AKS did not contain any provisions expressly conditioning Medicare payments on compliance with the AKS, and that such a provision was only added in the 2010 Patient Protection and Affordable Care Act. This contention is both irrelevant and befuddling. The Medicare Provider Agreement, which all medical providers must sign in order to be eligible for reimbursements from Medicare, requires that each provider certify that he/she is complying with the AKS, which prohibits the types of kickbacks alleged in the SAC. SAC ¶¶ 35-36. Additionally, the certification is a continuing certification, meaning that by signing, the providers attest to meeting and maintaining the standards to which they certify (i.e. that they are not receiving, and will not receive, kickbacks). *Id.* Moreover, the claim forms themselves contain a similar certification; therefore, each time a provider submits a claim for payment to Medicare, he or she must again certify compliance with the AKS. *Id. See also, e.g. Wilkins*, 659 F.3d at 313 (Third Circuit holding unequivocally that "[c]ompliance with the AKS is clearly a condition of payment" under the federal health insurance programs.) (emphasis added).

g. This complaint is not barred by the statute of limitations

In yet another footnote, GSK argues that since Relator first began working at GSK in 1997, any claims that he might have had knowledge of may have been barred by the 6-year statute of limitations. This is again meritless. Relator's initial complaint in this action was filed on November 9, 2006. None of the allegations were based on events prior to 2001. There is no statute of limitations issue here.

CONCLUSION

For the foregoing reasons, Relator respectfully requests that the Court deny GSK's motion to dismiss in its entirety.

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.
LAURENCE ROSEN (LR-5733)
PHILLIP KIM (PK-9384)
275 Madison Avenue, 34th Floor
New York, N.Y. 10016
Tel. 212-686-1060
Fax 212-202-3827
lrosen@rosenlegal.com
pkim@rosenlegal.com

Attorneys for Relator David Moore

DATED: February 28, 2013

CERTIFICATE OF SERVICE

I hereby certify that on this on the 28th day of February, 2013, a true and correct copy of the foregoing **Relator's Memorandum of Law In Opposition to GlaxoSmithKline LLC's Motion to Dismiss Relator's Second Amended Complaint** was served by CM/ECF to the parties registered to the Court's CM/ECF system.

/s/ Yu Shi